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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,219	01/23/2004	Wolfgang Dinkelacker	K0004/7005	9150

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LAW OFFICES OF PAUL E. KUDIRKA  
40 BROAD STREET  
SUITE 300  
BOSTON, MA 02109

EXAMINER
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WERNER, JONATHAN S

ART UNIT	PAPER NUMBER
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3732

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/764,219	<b>Applicant(s)</b> DINKELACKER, WOLFGANG	
	<b>Examiner</b> Jonathan Werner	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/21/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This action is in response to Applicant's amendment received on 12/21/06.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/06 has been entered.

#### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-9 and 11-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims appear to recite part of the human body in combination with the structure of the claimed invention, i.e. in claim 1

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and 18, Applicant claims the circumference of the molded piece "is in direct contact with the jaw tissue." Likewise, both claims 1 and 18 recite "the circumference is kept in close contact with the jaw tissue." It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 USC 101. The grant of limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). Applicant needs to clearly state using inferential language that the human anatomy is not claimed. For examination purposes, the claims will be considered as if such limitations involving the combination with a human were not present.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-9, 11-14 and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda (US 5,174,755). As to claims 1 and 18, Fukuda discloses a jaw implant comprising a screw (i.e. 11); an implant body (3a/4) having an implant head to which a superstructure is capable of being attached and a threaded bore (i.e. Figures 1, 5 and 9-10) extending from the implant head in the direction of a longitudinal axis of the implant body for engagement with the screw; and an attachment (7) capable of having jaw tissue above the implant head when the implant body is screwed deeper into the

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jaw bone of Figure 3, the attachment being fastened with the screw to the implant body (see embodiment of Figure 5) after the implant body has been inserted into a jawbone and before the superstructure is attached, whereby the embodiment shown in Figure 5 shows that the post (6) acts as the head portion of the fastening screw and is capable of fully covering the top of said attachment without the presence of a superstructure. The attachment also having a base part (bottom of 7); a head part (top of 7); and a molded piece made of a biocompatible and elastic material (column 5, line 37) located between the base part and the head part, the screw passing through the head part (Figure 5), the molded piece and the base part and engaging the threaded bore to generate axial pressure that enlarges the circumference so that it inherently expands outward along the side regions of the assembly (column 5, lines 52-55). Examiner notes that statements of intended use and other functional statements, i.e. using a permanent superstructure and a temporary attachment, do not impose any further structural limitations on the claims distinguishable over the prior art of record, of which, for example, the attachment can be replaced and thus acts as a temporary attachment. As to claims 2-3, the base part has a first surface shaped to fit closely to the implant head shape, and has a second surface in contact with the molded piece, wherein said second surface exhibits a wedge-shaped profile (Figure 5). As to claim 4, the head part has a surface that is in contact with the molded piece and has a shape profile which, under force from the screw, predetermines a form in which the circumference of the molded piece is enlarged depending on the direction of the applied force. In regard to claims 5 and 6, Figure 5 shows that the base part surface and the head part surface each have a

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convex shape profile which tapers toward the center of the molded piece. As to claims 7 and 8, the base part surface and the head part surface have radially asymmetric shape profiles as shown in Figure 5 and wherein at least one of the base part and the head part are capable of being rotated around the longitudinal axis of the implant. In regard to claims 9 and 20, as mentioned above, post 6 in Figure 5 acts as the screw head which bears directly against the molded piece. As to claims 11-12 and 21-22, the molded piece has a cylindrical shape and can have a height at least equal to a thickness of gingival tissue layer over the jawbone (as seen in Figure 3). As to claims 13 and 23, Fukuda discloses from incorporation by reference that it is known in the art to make the molded piece from silicone (column 1, lines 46-54). In regard to claim 14, the implant head serves as the base part and directly contacts the molded piece (see Figure 5). As to claim 16, both the head part and the base part are attached to the molded piece in Figure 5. As to claim 17, the embodiment of prior art incorporated by reference in Figure 12 shows it is known in the art that the threaded bore can receive the fastening screw without the presence of the elastic attachment. As to claim 19, Figure 5 further shows the implant head comprises a profile in the form of opposing slopes (located near the longitudinal center).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda in view of Perry (US 5,108,288). Fukuda discloses the dental implant as previously described above in detail, but fails to show that both the implant head and the base part have radially asymmetrical surfaces that interlock. Perry, however, teaches a dental implant in which both the implant head and a corresponding base of a locking sleeve both have asymmetrical surfaces (column 2, lines 41-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make both corresponding surfaces asymmetrical in order to lock the two pieces together to prevent rotation, movement and loosening of the fastening screw to the remainder of the restoration as taught by Perry.

### ***Response to Arguments***

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

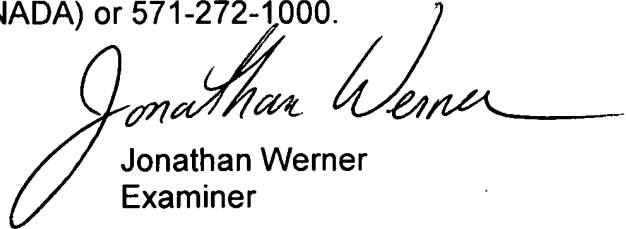
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Jonathan Werner  
Examiner

1/20/07

  
MELBA N. BUMGARNER  
PRIMARY EXAMINER